IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 05-340 (SLR) (consolidated)
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 05-360 (SLR) (consolidated)

DIRECT AND INDIRECT PURCHASER PLAINTIFFS' OPPOSITION TO MOTION FOR LEAVE TO FILE A MOTION FOR SUMMARY JUDGMENT ON ANTITRUST INJURY

In direct defiance of the Court's wishes as expressed at the April 3, 2008 status conference, Defendants have filed a motion seeking leave to relitigate the very issues Judge Jordan decided against them under the thinly veiled guise of addressing "antitrust injury." Defendants contend that Plaintiffs' antitrust claims are "fatally flawed in that Defendants' alleged actions expanded and did not limit consumer choice." Def. mot. at 2. Judge Jordan held otherwise. *See Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006) (by introducing new versions of TriCor and withdrawing prior versions, Defendants' alleged conduct effectively defeated consumer choice). Defendants' assertion that they do not intend to retread ground covered by Judge Jordan is refuted by their motion for leave. The motion should be denied.

I. DEFENDANTS ARE ATTEMPTING TO RELITIGATE LEGAL ISSUES ALREADY DECIDED BY JUDGE JORDAN.

At the recent status conference, this Court ruled that summary judgment motion practice would be limited to the issues of market power and the propriety of the patent litigations. After repeated pressing by Defendants' counsel, the Court stated that it would "go back and read

[Judge Jordan's] opinion" and that, unless the Court found that the legal issues Defendants wished to raise on summary judgment had not been decided by Judge Jordan, the Court's ruling would stand. Tr. at 41-42. Defendants' counsel responded: "I understand, Your Honor." *Id.* at 42.

Several weeks have passed, and the Court has not notified the parties that it intends to expand the issues subject to summary judgment briefing. Accordingly, the instructions given by the Court on April 3 remain in place. Defendants' motion for leave is in effect a motion for reconsideration and is no more persuasive than their oral attempts to persuade the Court to reconsider on April 3. *See Samuel v. Carroll*, 505 F. Supp. 2d 256, 261 (D. Del. 2007) ("A motion for reconsideration is not properly grounded on a request that a court rethink a decision already made") (Robinson, J.) Moreover, while Defendants attempt to clothe their arguments in the language of "antitrust injury," it is perfectly evident that, underneath those clothes, the legal arguments they seek to raise are the very arguments already rejected by Judge Jordan in 2006.

Plaintiffs' antitrust claims arise out of Defendants' scheme to suppress generic competition by ensuring that, at the time less expensive generic versions of TriCor were approved by the FDA and became available to the public, there was no branded version of TriCor in the marketplace to which that generic version was AB-rated (and, hence, for which it could be substituted by retail pharmacies). *See Abbott Laboratories*, 432 F. Supp. 2d at 415-18. As Congress contemplated and encouraged through its enactment of the Hatch-Waxman Act, generic manufacturers like Teva and Impax compete with branded manufacturers like Abbott and Fournier by marketing less expensive AB-rated generic versions of branded drugs which can be (and are) substituted by retail pharmacies when a prescription is presented for the branded drug. *Id.* at 414-15. Abbott and Fournier intentionally interfered with that competition by making minor formulation

changes to TriCor shortly before FDA approval of an AB-rated generic version of TriCor and withdrawing the prior formulation from the market. They did so *twice*, once in 2001 and again in 2004. *Id.* at 415-18. These changes resulted in formulations that were merely bioequivalent to (and hence no improvement over) the prior formulation. *Id.* at 416, 418, 423. In each case, when a less expensive version of TriCor was approved by the FDA a few months later, no market existed for those generic drugs because Defendants had withdrawn the TriCor formulation for which the generic drug could be substituted and had actively converted all TriCor prescribers to the new formulation. *Id.* at 416, 418. As a result of this scheme, there has been no effective AB-rated generic competition to TriCor despite the fact that a generic version of the 200 mg TriCor capsule was approved by the FDA in 2002. As Judge Jordan noted, this alleged scheme effectively denied consumers a "choice between fenofibrate formulations." *Id.* at 422. "Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations." *Id.*

In their motion for leave, Defendants argue that no antitrust liability can flow from this scheme because Teva and Impax were not completely foreclosed from distributing their products and because the injury Plaintiffs have suffered flows from the regulatory scheme rather than from Defendants' conduct. Def. mot. at 2-3, 7-8. However, Defendants made exactly the same argument in their motion to dismiss and, in Part IV.A.3 of Judge Jordan's opinion, Judge Jordan expressly rejected it. *See Abbott Laboratories*, 432 F. Supp. 2d at 423. In denying Defendants' motion to dismiss, Judge Jordan found, based on settled Third Circuit law, that competitors need not be completely foreclosed from marketing and selling their products in order to trigger antitrust liability. Because Defendants' motion for leave simply ignores this portion of Judge Jordan's opinion, we quote it in full:

> Defendants next argue that their introduction of new fenofibrate formulations cannot be considered anticompetitive because it has not prevented Teva or Impax from selling fenofibrate. *Defendants are correct that, according to Plaintiffs' allegations, Teva and Impax have not been prevented from marketing the formulations that were the subject of their ANDAs, i.e., the old TriCor formulations. If it were true that an antitrust plaintiff had to show that competition were completely foreclosed, then Defendants' argument might have merit. However, that is not the correct legal standard.*
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> To show that conduct has an anticompetitive effect, "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005). Competitors need not be "barred from all means of distribution," if they are barred "from the cost-efficient ones." [*United States v.*] *Microsoft* [*Corp.*], 253 F.3d [34,] 64 [(D.C. Cir. 2001)]. Here, while Teva and Impax may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has been allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case.

Id. (emphasis supplied).

Judge Jordan also ruled that the injury resulting from Defendants' alleged scheme to suppress generic competition constitutes antitrust injury. *Id.* at 430-31. In fact, as Judge Jordan noted, Defendants *conceded* that, taken as a whole, the alleged scheme to suppress generic competition resulted in antitrust injury. *Id.* at 431 ("Defendants do not argue that Plaintiffs have failed to allege antitrust injury for their overall scheme claims taken as a whole").

Defendants' motion for leave to file an additional summary judgment motion is nothing more than a request to relitigate issues decided by Judge Jordan and should be denied.

II. DEFENDANTS' MOTION IS BASED ON A MISUNDERSTANDING OF ANTITRUST INJURY.

Aside from seeking to relitigate Judge Jordan's earlier decision, Defendants' motion is based on a fundamental misunderstanding of the concept of antitrust injury. As noted above, Defendants' current arguments focus on the conduct challenged by Plaintiffs and on whether that conduct constitutes a violation of the antitrust laws—the very issue already resolved by Judge Jordan. *E.g.*, Def. mot. at 2 ("Defendants did not prevent competitors from bringing to market copies of their old product formulations . . . and in fact *expanded* the choices available to consumers . . ."). This is also the issue addressed in the *Nexium* opinion, which (as Defendants acknowledge) explicitly *distinguishes* Judge Jordan's opinion in this case.[1] Defendants' arguments, and the principal case on which they rely, concern the question of what conduct is and is not permissible under the antitrust laws.

"The purpose of the antitrust injury requirement is different." *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 342 (1990). The concept of antitrust injury *assumes* the existence of an antitrust violation and focuses on the *relationship* between the plaintiff's injury and the anticompetitive harm caused by that violation. Antitrust injury "ensures that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place." *Id. See also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (plaintiff's injury must "flow[] from that which makes defendants' acts unlawful"); *Zenith Radio*

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[1] While the *Nexium* opinion ostensibly discusses "antitrust injury," it does not address the concept of antitrust injury as defined by the Supreme Court. The court's discussion of antitrust injury is simply a restatement of the court's prior determination that in that case, unlike this one, the defendant's conduct was not exclusionary.

Corp. v. Hazeltine Research, 395 U.S. 100, 125 (1969) (plaintiff's injury must be "the type of loss that the claimed violations . . . would be likely to cause").

When properly framed, the existence of antitrust injury is not a difficult question in this case. *If* the exclusionary scheme alleged by Plaintiffs violates the antitrust laws (as Judge Jordan held it does), there is no serious question that the harm claimed by these Plaintiffs—paying higher prices for fenofibrate products—*perfectly* reflects the rationale for finding a violation of the antitrust laws in the first place. And in fact the Third and Sixth Circuits have so held. *See In re Warfarin Sodium Antitrust Litigation*, 214 F.3d 395, 401 (3d Cir. 2000) (higher prices paid by purchasers of drug as a result of suppression of generic competition constitutes antitrust injury: "It is difficult to imagine a more formidable demonstration of antitrust injury");[2] *In re Cardizem CD Antitrust Litigation*, 332 F.3d 895, 911 (6th Cir. 2003) ("[u]nlike in *Brunswick*, here there is no question that the alleged injury—paying higher prices for a product due to a lack of competition in the market—is the type of injury that can . . . flow from the anticompetitive effects of" the defendants' unlawful conduct).

III. CONCLUSION

While framed in terms of antitrust injury, the arguments Defendants seek to raise relate to the existence of an antitrust violation and have already been rejected by Judge Jordan. Moreover, the concept of antitrust injury, properly understood, is not a genuine issue in this case. Defendants' motion for leave should be denied.

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[2] The allegation in *Warfarin* was that the manufacturer of Coumadin had taken steps to "discourag[e] consumers from switching to lower priced generic warfarin sodium" but had not foreclosed generic competition entirely. *See In re Warfarin Sodium Antitrust Litigation*, 212 F.R.D. 231, 248 (D. Del. 2002).

Respectfully submitted,

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CERTIFICATE OF SERVICE

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